

## **REMARKS**

This Amendment is in response to the Examiner's Office Action mailed on June 4, 2003. Claims 3, 5, 29, and 31-38 are withdrawn. Claims 2, 6-7, 15, 39-43 are cancelled. Claims 4, 18, 20-22, and 28 are amended. Claims 1, 4, 8-14, 16-28 and 30 are now pending.

Reconsideration is respectfully requested in view of the above amendments to the claims and following remarks.

### **I. Claim Objection**

Applicant amended claim 28 to provide a method further comprising administering one or more antibiotic agents as suggested by the Examiner. Withdrawal of the objection is therefore respectfully requested.

### **II. Claim Rejection-Obviousness Type Double Patenting**

The Examiner rejected claims 1, 4, 6-14, 16-18, 28 and 30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 25, 29, 33, 34, 45 and 46 of copending Application No. 09/790,483 which has an issue date of September 2, 2003 and a patent number 6,613,753 (referred to herein as the "'753 patent").

In the instant application, claims 1, 4, 6-14, 16-18, 28 and 30 cover a combination therapy comprising administering to a patient 1 to 50 mg/m<sup>2</sup> per day of a **DNA methylation inhibitor** in combination with an effective amount of a **histone deacetylase inhibitor**. Claims 20, 25, 29, 33, 34, 45 and 46 of the '753 patent cover a method for treating a patient with a combination treatment of 1-20 mg/m<sup>2</sup> of **decitabine** and an effective amount of an **anti-neoplastic agent** to treat ovarian, breast, prostate, gastric, lung, pancreas, or colon cancer.

Applicant respectfully traverses Examiner's rejection for obviousness. While the current application claims the use of a DNA methylation inhibitor in combination with a histone deacetylase inhibitor, the '753 patent does not disclose or suggest such combination. In fact, the phrase "histone deacetylase inhibitor" does not even appear in the specification or claims of the '753 patent.

Further, neither *Zhu et al.* nor *Saito et al.* teaches or suggests the claimed method of administering to a patient 1 to 50 mg/m<sup>2</sup> per day of a DNA methylation inhibitor in combination with an effective amount of a histone deacetylase inhibitor. Thus the combination of the three references does not render the claimed invention obvious. However, to expedite prosecution, Applicants submit herewith a Terminal Disclaimer over 09/970,483. Withdrawal of the rejection is therefore respectfully requested.

### **III. Claim Rejection-35 U.S.C. § 112, First Paragraph**

The Examiner rejected claims 1, 4, 6-14, 16-28 and 30 under 35 U.S.C. 112, First Paragraph for lack of enablement for treatment of all cancers. According to the examiner, “while **being enabling** for a method of treating a specific cancer such as breast, lung, stomach or thyroid cancer,” the specification does not enable all other cancers. *See* Office Action, Paper 11, Page 5.

In order to make a rejection under the enablement requirement of 35 U.S.C. 112, First Paragraph, “the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.” *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993); MPEP 2164.04. In particular, the examiner must,

“explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971); MPEP 2164.04.

Furthermore, “[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” MPEP 2164.02.

As stated by the Examiner, the Specification **is enabling** for cancers such as breast, lung, stomach and thyroid. Examiner has not satisfied the requirement of establishing a reasonable basis to question the enablement for all other cancers. As the Examiner has not met the initial burden of explaining why all other cancers are not enabled, Applicant need not support the presumptively accurate disclosure. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. 112, First Paragraph.

**IV. Claim Rejection-35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claims 1, 4, 6-14, 16-28 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to claim an essential step - "the outcome of the treatment." See Office Action, Paper 11, page 9.

According to the MPEP, "[a] claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, **first paragraph**, as not enabling." See MPEP 2172.01 (emphasis added). In determining whether an unclaimed feature is essential or critical, the **entire** disclosure must be considered. "Features which are merely preferred are not to be considered critical." *In re Goffee*, 542, F.2d 564, 567 (CCPA 1976); MPEP 2164.08(c).

In this case, Applicant did not disclose an "outcome of the treatment" because the outcome is not critical. Treatment outcome, according to the present invention can include cancer growth arrest, attenuation in cancer growth, or complete cure of cancer, to name just a few features of the outcome of the treatment. As there is no particular feature of the "outcome of treatment" which is critical to the claimed invention, it is not necessary for the applicant to claim such limitation. Therefore, Applicant respectfully traverses the Examiner's rejection under 35 U.S.C. 112, second paragraph, and requests that the Examiner withdraw this rejection.

**CONCLUSION**

Applicants believe that they are entitled to a letters patent and respectfully solicit the Examiner to expedite prosecution of this patent to issuance. Should the Examiner have any questions, Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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